

TENT COOPERATION TRE Y

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 31 October 2000 (31.10.00)	
International application No. PCT/US99/11906	Applicant's or agent's file reference 1572.0001
International filing date (day/month/year) 28 May 1999 (28.05.99)	Priority date (day/month/year) 26 February 1999 (26.02.99)
Applicant SINGH, Manmohan et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

23 September 2000 (23.09.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer F. Baechler
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38



From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

To:

DOLLARD, Anne S.
CHIRON CORPORATION
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)	20.04.2001
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Applicant's or agent's file reference 1572.100	IMPORTANT NOTIFICATION
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International application No. PCT/US99/11906	International filing date (day/month/year) 28/05/1999	Priority date (day/month/year) 26/02/1999
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Applicant CHIRON CORPORATION et al.
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- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

DOCKETED 4/30/01 MD
Atty. ASD
File # 1572.100
Due Date _____
Final Date 8/26/01 - NP2

Name and mailing address of the IPEA/ European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Neumann, M Tel. +49 89 2399-7351
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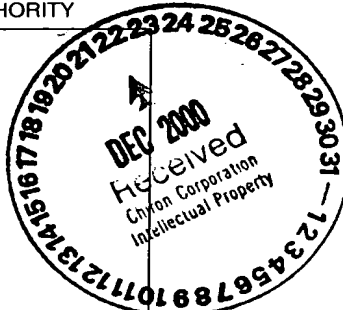


PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

DOLLARD, Anne S.
CHIRON CORPORATION
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097
ETATS-UNIS D'AMERIQUE



PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing (day/month/year) 18.12.2000	
Applicant's or agent's file reference 1572.100	REPLY DUE within 3 month(s) from the above date of mailing
International application No. PCT/US99/11906	International filing date (day/month/year) 28/05/1999
Priority date (day/month/year) 26/02/1999	
International Patent Classification (IPC) or both national classification and IPC A61K39/39	
Applicant CHIRON CORPORATION et al.	

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain document cited
 - VII ☒ Certain defects in the international application
 - VIII ☒ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **26/06/2001**.

DOCKED on/by 12/22/00 WMS
 Adv. ASD PA
 File # 1572.100
 Date 3/18/01 Ext R512

Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer / Examiner <u>for 1st opinion</u> Tilkorn, A-C Formalities officer (incl. extension of time limits) Danti, B Telephone No. +49 89 2399 8161
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WRITTEN OPINION

International application No. PCT/US99/11906

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-27 as originally filed

Claims, No.:

1-32 as originally filed

Drawings, sheets:

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

WRITTEN OPINION

International application No. PCT/US99/11906

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 16-22, 24-27, 29-31 with regard to industrial applicability,

because:

- ☒ the said international application, or the said claims Nos. 16-22, 24-27, 29-31 with regard to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the said claims Nos. .

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement
Novelty (N) Claims 1-32
Inventive step (IS) Claims

WRITTEN OPINION

International application No. PCT/US99/11906

Industrial applicability (IA) Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item III

Claims 16-22,24-27,29-31 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

The following documents are referred to in this communication:

- D1: WO 94 20070 A
- D2: WO 95 17211 A
- D3: EP-A-0 304 786
- D4: GIULIANI M M, ET AL.: 'Mucosal Adjuvancidity and Immunogenicity of LTR72, a Novel Mutant of Escherichia coli Heat-labile Enterotoxin with Partial Knockout of ADP-ribosyltransferase Activity' JOURNAL OF EXPERIMENTAL MEDICINE, [Online] vol. 187, no. 7, 6 April 1998 (1998-04-06), pages 1123-1132, XP002118943 ISSN: 0022-1007 Retrieved from the Internet: <URL:http://intl.jem.org/content/vol187/is_sue7/index.shtml> [retrieved on 1999-10-14]

1 **Novelty (Art 33(2) PCT):**

None of the present claims is novel:

Claim 1 is anticipated by D1 (p 10 para 3), D2, (abstract, col 3 l 30-40), D3 (abstract, p 10 l 3-5, p 11 l 15-16), D4 (abstract; p 15 l 11- p 16 l 29; Examples 10, 13, 14).

D1 also anticipates **claims 2** (p 13 l 1-2), **3** (p 12 para 3), **4, 7, 9, 10** and **32** (D1: claims 4-7), **5** and **6** (p 8 para 1 ff), **11 -13** (p 2 para 1; p 4 para 2), **14-31** (abstract, p 11 para 2).

D2 also prejudices the novelty of **claims 3** (col 3 l 26-40); **4-6** (col 6 l 28-34; claim 1), **11-13** (col 6 l 1-5), **14,15** (col 6 l 6-11), **16-31** (col 7 l 34-36, l 46-47).

D3 also destroys novelty of **claims 3** and **5** (abstract, p 10 l 3-5, p 11 l 15-16), **7** (p 5 l 13-18, p 10 l 15- p 11 l 8), **8** (p 6 l 29-35, p 10 l 22, 34), **9, 10** and **32** (p 8 l 7-23), **11, 12** (p 7 l 9-14, p 10 l 25), **14, 15** (p 5 l 19-21), **16-31** (p 7 l 18-24, 35 ff).

D4 also takes away the novelty of **claims 3-6** (abstract; p 15 l 11- p 16 l 29), **7** (p 3 l 34), **9** and **32** (p 14 l 16-34), **11-13** (p 3 l 32- p 4 l 3, l 26-33), **17, 19, 21, 29-31** (claims 36, 38).

2 Industrial Applicability (Art 33(4) PCT):

For the assessment of the present **claims 16-22,24-27,29-31** on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

The applicant is requested to file amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate.

Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 34(2)(b) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

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REC'D 24 APR 2001

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1572.100	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/11906	International filing date (day/month/year) 28/05/1999	Priority date (day/month/year) 26/02/1999
International Patent Classification (IPC) or national classification and IPC A61K39/39		
Applicant CHIRON CORPORATION et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 23/09/2000	Date of completion of this report 20.04.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Tilkorn, A-C Telephone No. +49 89 2399 8688 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/11906

I. Basis of this report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-27 as originally filed

Claims, No.:

1-32 as originally filed

Drawings, sheets:

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/11906

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 16-22,24-27,29-31 with regard to industrial applicability.

because:

☒ the said international application, or the said claims Nos. 16-22,24-27,29-31 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims -

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/11906

	No:	Claims	1-32
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-32
Industrial applicability (IA)	Yes:	Claims	1-15,23,28,32
	No:	Claims	-

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US99/11906

Re Item III

Claims 16-22,24-27,29-31 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

The following documents are referred to in this communication:

D1: WO 94 20070 A

D2: WO 95 17211 A

D3: EP-A-0 304 786

D4: GIULIANI M M, ET AL. JOURNAL OF EXPERIMENTAL MEDICINE, [Online]
vol. 187, no. 7, 6 April 1998 (1998-04-06), pages 1123-1132, XP002118943
ISSN: 0022-1007 Retrieved from the Internet:
<URL:http://intl.jem.org/content/vol187/is_sue7/index.shtml> [retrieved on
1999-10-14]

1 Novelty (Art 33(2) PCT):

None of the present claims is novel:

Claim 1 is anticipated by D1 (p 10 para 3), D2, (abstract, col 3 l 30-40), D3 (abstract, p 10 l 3-5, p 11 l 15-16), D4 (abstract; p 15 l 11- p 16 l 29; Examples 10, 13, 14).

D1 also anticipates **claims 2** (p 13 l 1-2), **3** (p 12 para 3), **4, 7, 9, 10** and **32** (D1: claims 4-7), **5** and **6** (p 8 para 1 ff), **11 -13** (p 2 para 1; p 4 para 2), **14-31** (abstract, p 11 para 2).

D2 also prejudices the novelty of **claims 3** (col 3 l 26-40); **4-6** (col 6 l 28-34; claim 1), **11-13** (col 6 l 1-5), **14,15** (col 6 l 6-11), **16-31** (col 7 l 34-36, l 46-47).

D3 also destroys novelty of **claims 3** and **5** (abstract, p 10 l 3-5, p 11 l 15-16), **7** (p 5 l 13-18, p 10 l 15- p 11 l 8), **8** (p 6 l 29-35, p 10 l 22, 34), **9, 10** and **32** (p 8 l 7-23), **11, 12** (p 7 l 9-14, p 10 l 25), **14, 15** (p 5 l 19-21), **16-31** (p 7 l 18-24, 35 ff).

D4 also takes away the novelty of **claims 3-6** (abstract; p 15 l 11- p 16 l 29), **7** (p 3 l 34), **9** and **32** (p 14 l 16-34), **11-13** (p 3 l 32- p 4 l 3, l 26-33), **17, 19, 21, 29-31** (claims

36, 38).

2 Industrial Applicability (Art 33(4) PCT):

For the assessment of the present **claims 16-22,24-27,29-31** on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VII

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1- D4 are not mentioned in the description, nor are these documents identified therein.

In order for the application to be self-contained the reference to non-published patent applications (e.g. p 7 I 8-9; p 16 I 31-32) should have been replaced by the corresponding publication numbers (Guidelines II 4.17).

The expression "incorporated herein by reference" in respect of prior art documents (e.g. page 7 I 10; p 14 I 5-6) leads to a doubt as to whether the requirement of the description being self-contained is satisfied (Guidelines II, 4.17).

The last sentence on page 27 should have been deleted as it contains general statements which imply that the extent of protection may be expanded in some vague and not precisely defined way (Guidelines III 4.3a).

Re Item VIII

Independent **claims 14-31** do not comply with the requirement of conciseness (Art 6 PCT; Guidelines III 5.1).

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 1572.0001	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 99/ 11906	International filing date (day/month/year) 28/05/1999	(Earliest) Priority Date (day/month/year) 26/02/1999
Applicant CHIRON CORPORATION et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.



None of the figures.

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Remark: Although claims 16-22, 24-27 and 29-31 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. ☒ Claims Nos.: 1, 2, 11, 14-27
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1, 2, 11, 14-27

Present claims 1, 2, 11, 14-27 relate to an extremely large number of possible compounds/methods. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds/methods claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the compounds/methods as disclosed in the example, and as claimed in claims 3-10, 12, 13. Furthermore the general concept of the invention has been searched.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International Application No

US 99/11906

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K39/39 A61K39/145 A61K9/00 A61K9/16 A61P31/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 42375 A (CHIRON CORP) 1 October 1998 (1998-10-01) page 4, line 1 -page 5, line 23 page 19, line 13 - line 23 page 22, line 4 -page 25, line 7 claims; figure 2; example 5; table 6 ---	1,3-10, 14-32
X	WO 94 20070 A (SECRETECH INC ;DUNCAN JACQUELINE D (US); SCHAFER DENNIS P (US)) 15 September 1994 (1994-09-15)	1-10, 14-32
Y	page 2, line 22 -page 3, line 3 page 5, line 6 -page 6, line 7 page 8, line 1 - line 29 page 8, line 30 -page 10, line 16 page 12, line 24 - line 36 claims; examples --- -/--	1-32

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

15 October 1999

Date of mailing of the international search report

29/10/1999

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>GIULIANI M M, ET AL.: "Mucosal Adjuvancidity and Immunogenicity of LTR72, a Novel Mutant of Escherichia coli Heat-labile Enterotoxin with Partial Knockout of ADP-ribosyltransferase Activity"</p> <p>JOURNAL OF EXPERIMENTAL MEDICINE, 'Online! vol. 187, no. 7, 6 April 1998 (1998-04-06), pages 1123-1132, XP002118943</p> <p>ISSN: 0022-1007</p> <p>Retrieved from the Internet: <URL:http://intl.jem.org/content/vol187/is sue7/index.shtml></p> <p>'retrieved on 1999-10-14!</p> <p>the whole document</p> <p>---</p>	1-10, 14-32
Y	<p>US 5 707 644 A (ILLUM LISBETH)</p> <p>13 January 1998 (1998-01-13)</p> <p>column 2, line 18 - line 38</p> <p>column 3, line 26 - line 40</p> <p>column 6, line 1 - line 42</p> <p>column 8, line 14 - line 23</p> <p>column 9, line 15 - line 35; example 3</p> <p>---</p>	1-6, 9-15, 23
X	<p>WO 95 17211 A (BIOCINE SPA ;RAPPUOLI RINO (IT)) 29 June 1995 (1995-06-29)</p> <p>page 5, line 13 -page 8, line 23</p> <p>page 9, line 36 -page 11, line 21</p> <p>page 13, line 1 -page 17, line 44; figures claims 1-9</p> <p>---</p>	1,3,5, 7-12, 14-32
X	<p>EP 0 304 786 A (MOBAY CORP)</p> <p>1 March 1989 (1989-03-01)</p> <p>page 3, line 41 - line 57</p> <p>page 4, line 22 - line 45</p> <p>claims; figures; examples; tables</p> <p>---</p>	1-4,7,9, 10,14-32
X	<p>WO 95 11700 A (PHARMOS CORP ;US GOVERNMENT (US); LOWELL GEORGE H (US); AMSELEM SH)</p> <p>4 May 1995 (1995-05-04)</p> <p>page 7, line 1 -page 9, line 20</p> <p>page 14, line 12 -page 17, line 3</p> <p>claims 1,13,14,24-27; examples 1,3,10</p> <p>-----</p>	1,3-7,9, 14-32

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

/US 99/11906

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